UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the month of November 2019

Commission File Number: 001-37773

Merus N.V.

(Translation of registrant's name into English)

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Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

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Business Update

MCLA-128

On October 25, 2019, Merus N.V. ("we" and "our") and investigators at Memorial Sloan Kettering Cancer Center, or MSKCC, announced acceptance of a presentation entitled "Clinical proof-of-concept for MCLA-128, a bispecific HER2/3 antibody therapy, in NRG1 fusion-positive cancers" that was presented at AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics on October 27, 2019 in Boston, Massachusetts, or the triple meeting.

On October 27, 2019, investigators from MSKCC provided an oral presentation at the triple meeting also entitled "Clinical proof-of-concept for MCLA-128, a bispecific HER2/3 antibody therapy, in NRG1 fusion-positive cancers", reporting a summary and initial data concerning the treatment of three cancer patients harboring NRG1 fusions with MCLA-128 at 750 mg administered intravenously every other week. These patients' NRG1 gene fusions were identified using RNA-based sequencing. Assessments from this Early Access Program, or EAP, were conducted locally at MSKCC. All three patients exhibited tumor shrinkage, symptomatic improvement and durability up to their most recent assessment. All three patients remain on treatment as of October 29, 2019. Two of the EAP patients have pancreatic ductal adenocarcinoma, or PDAC, with one exhibiting a 54% reduction in tumor diameter at a confirmatory 5 months scan (partial response, or PR, by RECIST v1.1), and the other exhibiting a 25% reduction in tumor diameter at a confirmatory 5 months scan (stable disease, or SD, by RECIST v1.1). Both patients remain on treatment for over 7 months as of October 29, 2019. In the first patient, Positron Emission Tomography, or PET, imaging showed no evidence of metabolically active tumor and a relevant serum biomarker showed improvement within the first four weeks. Also within weeks of the first dose, the patient's symptoms, including fatigue and weight loss, improved. In the second patient, PET imaging showed no evidence of metabolically active tumor. The patient's tumor-related abdominal pain also improved following treatment. A third EAP patient treated at MSKCC has non-small cell lung cancer, or NSCLC, and exhibited a 41% reduction in tumor diameter at a confirmatory scan (PR by RECIST v1.1) and improvement in brain metastases. Prior to MCLA-128 treatment the patient progressed on six lines of therapy, including the tyrosine kinase inhibitor afatinib. The patient remains on treatment for approximately 5 months as of October 29, 2019.

On October 27, 2019, we also provided an update regarding MCLA-128 safety and tolerability in the Phase 1/2 clinical trial as of January 2019, wherein 117 patients treated with single-agent MCLA-128 with dosing regimens ranging from weekly to once every three weeks, reported mostly mild to moderate adverse events, or AEs. The incidence of grade 3 and 4 AEs irrespective of causality was 37% and 3%, respectively, with the incidence of suspected drug-related grade 3 AEs of about 4%, and no grade 4 events. One patient experienced a grade 5 hypersensitivity reaction, which was previously reported in Alsina et al. ESMO. 2018 #664P. As of October 29, 2019, the safety results for MCLA-128 in patients with cancers harboring NRG1 fusions have been consistent with what has been previously reported in the overall patient population treated with MCLA-128.

We further provided an overall update on our MCLA-128 EAP and Phase 1/2 trial amended in June 2019 to focus on patients with solid tumors harboring an NRG1 fusion (eNRGy). As of October 27, 2019, nine patients identified with cancers harboring NRG1 fusions (three PDAC patients and six NSCLC patients) had been enrolled and treated with MCLA-128 across the EAP and eNRGy trial. Of the nine patients treated, six had at least one evaluation and all patients had previously progressed through standard of care.

Two PDAC patients were treated under the EAP (single patient investigational new drug applications, or INDs) at MSKCC as noted above. A third EAP PDAC patient was enrolled under a single patient IND outside of MSKCC. The patient received two treatments with MCLA-128, at a four-week non-standard interval due to the severity of the patient's illness, and was non-evaluable, passing away due to complications related to the underlying disease prior to a first tumor evaluation.

Of the six NSCLC patients, one patient was treated under the EAP as noted above. The other five patients were enrolled in the MCLA-128 eNRGy clinical trial. Of these, one patient had SD for greater than 7 months but discontinued the trial due to poor adherence to the treatment protocol (unrelated to any AE or lack of efficacy); two patients had progressive disease and are no longer on the trial; and two patients have only recently started treatment and have not yet been assessed for response.

On October 27, 2019, we also provided an update regarding our MCLA-128 Phase 2 trial, noting following enrollment completion, we do not have plans to advance into a Phase 3 clinical trial in metastatic breast cancer or gastric cancer in the absence of a collaborator and intend instead to refocus efforts on the MCLA-128 eNRGy trial as well as our other clinical and late-stage preclinical pipeline programs.

In patients enrolled as of August 31, 2019, we conducted an unplanned interim efficacy analysis with a data cut-off of October 23, 2019. For this analysis, Disease Control Rate, or DCR, which is the proportion of patients at first scheduled assessment who have achieved complete response, or CR, PR and or SD as the best overall response to therapy, and Overall Response Rate or ORR, which is the proportion of patients who have a partial or complete response as the best overall response to therapy, were estimated in both cohorts, "HER2+" and "ER+/HER2^{low}", in our Phase 2 combination trial in metastatic breast cancer. Patients in the metastatic breast cancer trial were not evaluated for NRG1 fusions. In the HER2+ cohort, 24 patients were treated with MCLA-128 and a combination of trastuzumab and vinorelbine, and the estimated DCR observed was 75%. The estimated ORR was 4% (confirmed) and 17% (unconfirmed) including 3 PRs and 1 CR. All patients were previously treated with trastuzumab, pertuzumab, and an anti-HER2 antibody drug conjugate. The median number of prior lines of anti-HER2 therapy in the metastatic setting was three and 71% of patients had visceral involvement. In the ER+ cohort, 40 patients were treated with MCLA-128 and continuation of endocrine therapy on which they progressed prior to study entry, and the estimated DCR observed was 40%. The ORR was 0%. All patients were previously treated with CDK4/6 inhibitors. The median number of prior lines of endocrine therapy in the metastatic setting was two and 85% of patients had visceral involvement.

Enrollment in the ER+ cohort is now closed, having reached the minimum target accrual of 40 patients. We plan to continue to enroll another approximately 10 patients in the HER2+ cohort to reach the target accrual. We expect to present mature results, including the primary endpoint of clinical benefit rate at 24 weeks for both cohorts in this trial at a medical conference in 2020.

NRG1 Fusions

The NRG1 gene encodes for neuregulin (also known as heregulin), the ligand for HER3. Fusions between NRG1 and partner genes are rare, genetic events occurring in patients with certain lung, pancreatic and other solid tumors, associated with activation of HER2/HER3 signaling and growth of cancer cells. Overall projections for NRG1 fusions occurrence are based on limited published information at present. Based on the current literature available, we estimate that NRG1 fusions occur at a rate of approximately 0.3% - 3.0% in NSCLC, 0.5% - 1.5% in PDAC, and less than 1% in all other tumor types.

In preclinical studies, the mechanism by which the NRG1 fusion protein stimulates tumor growth has been observed to be especially sensitive to inhibition by the MCLA-128 Dock & Block® mechanism of binding (docking) to HER2 and blocking the interaction of HER3 with its ligand neuregulin or with the NRG1 fusion protein. In preclinical studies, we have observed that MCLA-128 is capable of potent inhibition of neuregulin-driven HER2/HER3 heterodimer formation and tumor growth in models harboring NRG1 fusions.

MCLA-117

Dose escalation in our Phase 1 clinical trial for MCLA-117 for the treatment of acute myeloid leukemia is ongoing and preliminary anti-tumor activity has been observed. In July 2019, we amended the MCLA-117 protocol to allow for the exploration of higher doses. We initiated the Phase 1 trial at a low dose level based on the potent nature of T-cell engagers. Due to this amendment and continued dose escalation, we plan to present initial data from this trial at a medical conference in the first half of 2020.

MCLA-158

Dose escalation in the Phase 1 clinical trial of MCLA-158 in patients with solid tumors is ongoing. We expect emerging data for the Phase 1 trial, including safety and information around the recommended Phase 2 dose, at the end of 2019. We plan to provide further guidance on the program in 2020.

MCLA-145

In May 2019, we commenced a Phase 1 clinical trial evaluating safety, tolerability, and preliminary efficacy of MCLA-145 for the treatment of patients with advanced solid tumors. The Phase 1, open-label, single-agent clinical trial of MCLA-145 consists of dose escalation followed by dose expansion. The primary objectives of the Phase 1 trial are dose finding and evaluation of safety and tolerability in patients with advanced solid tumors. The Phase 1 trial will also examine potential preliminary antitumor activity and functional target engagement of single-agent MCLA-145. MCLA-145 is the first product candidate co-developed under our global research collaboration with Incyte.

MCLA-129

On October 25, 2019, we announced acceptance of a presentation entitled “Preclinical evaluation of MCLA-129: a bispecific antibody targeting c-MET and EGFR” that was presented at the triple meeting on October 29, 2019. MCLA-129 is an ADCC-enhanced Biclonics® that inhibits the EGFR and c-MET signaling pathways in solid tumors. Preclinical data has shown that MCLA-129 reverses resistance to tyrosine kinase resistant NSCLC cell lines resulting in tumor growth inhibition in xenograft models of NSCLC. MCLA-129 is designed to have two complementary mechanisms of action: blocking growth and survival pathways to stop tumor expansion and recruitment and enhancement of immune effector cells to eliminate the tumor.

Risk Factors

Risks Related to the Development and Clinical Testing of Our Bispecific Antibody Candidates

We depend on enrollment of patients in our clinical trials for our bispecific antibody candidates. If we are unable to enroll patients in our clinical trials, our research and development efforts and business, financial condition and results of operations could be materially adversely affected.

Successful and timely completion of clinical trials will require that we enroll a sufficient number of patient candidates. For the MCLA-128 Phase 2 clinical trial, we plan to enroll approximately 80 patients with metastatic breast cancer in the United States and Europe. In the Phase 1 clinical trial of MCLA-117, we plan to enroll approximately 50 adult patients with AML. In the Phase 1 clinical trial of MCLA-158, we plan to enroll approximately 120 adult patients with colorectal cancer and possibly other solid tumors. In the planned Phase 1 clinical trial of MCLA-145, we plan to enroll approximately 118 adult patients with solid tumors. These trials and other trials we conduct may be subject to delays as a result of patient enrollment taking longer than anticipated or patient withdrawal. For example, our Phase 1/2 single-agent trial of MCLA-128 in solid tumors is enrolling patients harboring neuregulin 1, or NRG1, gene fusions. Patient populations with solid tumors with NRG1 gene fusions are small, which could result in slow enrollment of clinical trial participants.

Our clinical trials will also compete with other clinical trials for antibody candidates that are in the same therapeutic areas as our bispecific antibody candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators and clinical trial sites is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites.

Patient enrollment depends on many factors, including the size and nature of the patient population, eligibility criteria for the trial, the proximity of patients to clinical sites, the design of the clinical protocol, the availability of competing clinical trials, the availability of new drugs approved for the indication the clinical trial is investigating, and clinicians’ and patients’ perceptions as to the potential advantages of the drug being studied in relation to other available therapies. These factors may make it difficult for us to enroll enough patients to complete our clinical trials

in a timely and cost-effective manner. Delays in the completion of any clinical trial of our bispecific antibody candidates will increase our costs, slow down our bispecific antibody candidate development and approval process, delay or potentially jeopardize our ability to commence product sales and generate revenue and harm our reputation and ability to obtain financing. In addition, some of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our bispecific antibody candidates**.**

Risks Related to Our Common Shares

As of the end of our most recent second fiscal quarter, we did not meet the requirements for being a foreign private issuer and, as of January 1, 2020, we will be required to comply with the provisions of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the rules of The Nasdaq Global Market, or Nasdaq, applicable to U.S. domestic issuers, which will require us to incur significant expenses and expend time and resources.

As of the end of our most recent second fiscal quarter, we did not meet the requirements for being a foreign private issuer. As a result, as of January 1, 2020, we will be required to comply with all of the provisions applicable to a U.S. domestic issuer under the Exchange Act, including filing an annual report on Form 10-K, quarterly periodic reports and current reports for certain events, complying with the sections of the Exchange Act regulating the solicitation of proxies, requiring insiders to file public reports of their share ownership and trading activities and insiders being liable for profit from trades made in a short period of time. We will also be required to comply with the rules of Nasdaq applicable to U.S. domestic issuers, including that our articles of association specify a quorum of no less than one-third of our outstanding voting common shares for meetings of our common shareholders, the solicitation of proxies and the approval by our shareholders in connection with certain events such as the acquisition of stock or assets of another company, the establishment of or amendments to equity-based compensation plans for employees, a change of control and certain private placements. In addition, we will be required to report our financial results under U.S. Generally Accepted Accounting Principles, including our historical financial results, which have previously been prepared in accordance with International Financial Reporting Standards. We expect to incur significant legal, accounting, insurance and other expenses and to expend greater time and resources, as we prepare for compliance, and comply, with these requirements.

We may be classified as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes, which could result in adverse U.S. federal income tax consequences to U.S. investors in the common shares.

Based on the current and anticipated value of our assets, including goodwill, and the current and anticipated composition of our income, assets and operations, we do not believe we will be a PFIC for U.S. federal income tax purposes for our current taxable year. A non-U.S. company will be considered a PFIC for any taxable year if (i) at least 75% of its gross income is passive income (including interest income), or (ii) at least 50% of the value of its assets (based on an average of the quarterly values of the assets during a taxable year) is attributable to assets that produce or are held for the production of passive income. The value of our assets generally is determined by reference to the market price of our common shares, which may fluctuate considerably. In addition, the composition of our income and assets is affected by how, and how quickly, we spend the cash we raise, including the proceeds from this offering. It is possible the Internal Revenue Service could determine that we were a PFIC for our current taxable year. If we were to be treated as a PFIC for any taxable year during which a U.S. Holder (as defined in the section of this Prospectus Supplement entitled “Certain Material Tax Considerations For U.S. Holders”) holds a common share, certain adverse U.S. federal income tax consequences could apply to such U.S. Holder. See “Certain Material Tax Considerations For U.S. Holders.”

This Report on Form 6-K is hereby incorporated by reference into our Registration Statements on Form F-3 (File No. 333-233367 and File No. 333-233383) and Registration Statement on Form S-8 (File No. 333-230708).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Merus N.V.

Date: November 4, 2019

By: /s/ Ton Logtenberg
Name: Ton Logtenberg
Title: President, Chief Executive Officer and
Principal Financial Officer